PARENTERAL FORMULATION FOR EPOTHILONE ANALOGS

Abstract of the Invention

A process for formulating certain epothilone analogs for parenteral administration is disclosed wherein the analog is dissolved in a mixture of at least 50% by volume tertiary-butanol in water, the mixture is lyophilized, the resulting lyophilized product is packaged in one vial with a sufficient amount of solvent comprising anhydrous ethanol and a suitable nonionic surfactant in a second vial. All steps are carried out with protection from light. In use, the contents of the second or diluent vial are added to the lyophilized product and mixed to constitute the epothilone analog and the resulting solution is diluted with a suitable diluent to produce a solution for intravenous injection containing the epothilone analog in a concentration of from about 0.1 mg/mL to about 0.9 mg/mL. A preferred surfactant is polyethoxylated castor oil and a preferred diluent is Lactated Ringer's Injection.